Attorney Docket No. CONLINCO-

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Sæbo et al.

Serial No.:

09/544,084

Filed:

04/06/00

Group No.: 1617

Examiner: Wang

CONJUGATED LINOLEIC ACID COMPOSITIONS Entitled:

## **Declaration of Asgeir Sæbo**

Assistant Commissioner for Patents Washington, D.C. 20231

## CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

- I, Dr. Asgeir Sæbo, state as follows:
- 1. My present position is Director of Research, Natural AS.
- I have reviewed the above captioned patent application, of which I am an inventor, the 2. Office Action mailed July 23, 2001, and the Cook, Baltes, and Lievense patents cited as prior art.
- 3. After review of the cited references, I conclude that the references do not teach methods of producing conjugated linoleic acid suitable for oral consumption with alcoholate catalysts. In fact, only one of the cited references, Baltes, teaches the use of alcoholate catalysts for any purpose. It is my understanding that in the Office Action the Examiner states that "[t]he citation of Baltes et al. (U.S. Patent 3,162,658) is to show the level of ordinary skill in the art."
- 4. Contrary to the Examiner's opinion, the Baltes patent is not applicable to the present invention because the Baltes patent teaches methods of making CLA and conjugated linolenic

PATENT Attorney Docket No. CONLINCO-04286

acid (CLnA) for technical purposes such as drying oils and paint varnishes. In particular, Column 1, line 30 of the Baltes patent provides that "[t]he latter ones, namely the unconjugated polyethenoid acids occur in nature in large quantities, while conjugated polyethenoid acids are relatively seldom found in fats and oils of natural origin except for woods oils such as tung oil. The latter compound and also its derivatives are of great technical interest and therefore, many attempts were made to isomerize unconjugated polyethenoid acids to conjugated acids." The Baltes patent is solving the problem of providing substitute conjugated acids for naturally occurring conjugated acid sources such as tung oil. Therefore, the methods of the Baltes patent are intended to produce an oil suitable for the same purposes as tung oil. Tung oil is not edible and the tung tree is listed in the "Poisonous Plant Bibliography" of the United States Food and Drug Administration, Center for Food Safety & Applied Nutrition, Office of Plant and Dairy Food and Beverages. The intended use of the conjugated linoleic acids for technical purposes as opposed to nutritional purposes is further reaffirmed at Column 9, lines 47-60 of Baltes patent where it is stated that "[t]he compounds of conugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in may ways. . . . The polymers thus formed can be used as ingredients of lacquers or coating compositions in convential manners." Based on the disclosure of the Baltes, Cook and Lievense patents, one cannot conclude that the CLA resulting from the alcoholate catalysis process is suitable for use in products meant for oral consumption.

5. Other disclosure in the Baltes patent also indicates the insuitabity of the methods for the production of edible CLA. Conjugated acids are inherently unstable. Stability is related to the number of double bonds. The Baltes patent describes the conjugation of soybean oil (Examples 1, 2, 6, 8, 9, 10, and 11), cottonseed oil (Example 3), linseed oil (Examples 4 and 5), and fish oil (Example 7), all of which contain high levels of triunstaurated fatty acids. These oils are generally unsuitable for obtaining CLA for nutritional uses because the refinement results in products with substantial amounts of breakdown products and unwanted polymers, especially when conjugated. However, it is noted that the use of oils with high levels of triunsaturated fatty acids as starting materials for CLA and CLnA for technical purposes is preferred due to the superior drying properties of conjugated trienes.

PATENT
Attorney Docket No. CONLINCO-04286

6. I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dr. Asgeir Sæbo

Date: Oct 12 2001